K043438

SECTION VI: 510(k) SUMMARY
[as required by section 807.92(c)]

FEB 15 2005

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.296.3000
Facsimile:	610.296.4591
Contact Person:	Tim Stoudt
Title:	Manager, QA Engineering / RA
Date Submission Prepared:	December 7, 2004

B. Device Information:

Trade name:	Not assigned at the time of submission
Classification Name(s):	Catheter Introducer (21 CFR §870.1340)
Common or usual name(s):	Large bore splittable introducer kit, Hemostatic, peel-away, dialysis introducer

C. Legally marketed device to which equivalence is claimed:

Thomas Medical Products, Inc., Tear-away sheath introducer kit - k934901

D. Description of the device:

The Thomas Medical Products Inc. Large bore splittable introducer kit(s) consists of a splittable sheath introducer and appropriately sized vessel dilator. A hemostasis valve is incorporated at the proximal end of the sheath. The valve reduces blood loss through the sheath during the catheter / lead introduction. The 'splittable' function allows for removal of the sheath from the vascular system over the inserted catheter or lead and then removal the sheath from the lead by splitting the device along its' longitudinal axis.

The sheath is available packaged (1) sterile with an appropriately sized dilator, (2) sterile as a procedural convenience kit with an 18 gage XTW needle, guidewire, and 12 cc syringe, and (3) bulk non-sterile.

E. Intended use of the device:

The Large bore splittable introducer kit is intended to provide percutaneous access to the vascular system for the purpose of delivering various types of catheters, pacing leads, and defibrillator leads.

F. Summary of the technological characteristics of the device compared to the predicate device:

The technological characteristics of the device are the same as those of the predicate devices.

G. Substantial equivalence rationale:

The Thomas Medical Products Inc. Large bore splittable introducer kit has similar general intended use / indications for use and technological characteristics as other previously cleared devices. Therefore, based on these similarities, the Thomas Medical Products, Inc. Large bore splittable introducer kit is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2005

Mr. Tim Stoudt
Manager, QA Engineering/RA
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K043438
Trade/Device Name: Large Bore Splittable Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catheter
Regulatory Class: II
Product Code: DYB
Dated: January 17, 2005
Received: January 18, 2005

Dear Mr. Stoudt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Mc Kinney

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K043438

510(k) Number (if known): **K043438**

Device Name: **Large bore splittable introducer kit**

Indications for Use:

For the introduction of various types of pacing or defibrillator leads and catheters.

<AND>

For the introduction of various types of catheters.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna D. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043438